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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,172	08/07/2003	Wayne A. Border	66821-236	3802

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/638,172	BORDER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *3,4,8,9,11,12 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5-7, 10, 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 6/2/05, has been entered.
Claim 6 has been amended.

Claims 1-2, 5-7,10, and 13-15 as they read on methods of treating glomerulonephritis with anti-TGF-β antibodies are under consideration in the instant application.

Claims 3-4, 8-9, 11-12 and 16-18 have been withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected inventions.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's amendment, filed 6/2/05.
The rejections of record can be found in previous Office Action, mailed 12/3/04.

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Again, applicant should amend the first line of the specification to update the status of the priority documents.

4. Applicant's amended claims have obviated the previous rejection under 35 U.S.C.§ 112, second paragraph, with respect to the recitation of "suppressing the activity of TGF-β in antibodies"

5. Claims 1, 5-7, 10, 13 and 15 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Dasch et al. (U.S. Patent No. 5,772,998) (see entire document).

Upon reconsideration of applicant's arguments in conjunction with the disclosure of the appropriate priority documents of the prior art, the previous rejection under provision of 35 U.S.C. § 102(e) has been withdrawn as it applies to methods of treating glomerulonephritis with anti-TGF- β antibodies appears to be free of the prior art.

However, the claims are not limited to said "methods of treating glomerulonephritis with anti-TGF- β antibodies".

Accordingly, the rejection of the claimed methods not limited to said "methods of treating glomerulonephritis with anti-TGF- β antibodies" are maintained for the reasons of record.

Dasch et al. teach the use of TGF-β-specific antibodies to neutralize the effects of TGF-β, including lung fibrosis, liver cirrhosis fibrotic skin disorders and scarring (see entire document, including columns 5-6 and the Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat various fibrotic conditions with the same neutralizing TGF-β-specific antibodies encompassed by the claimed methods.

Although applicant argues that the examiner has not met the burden of determining the inherent characteristics of the prior art teachings, applicant has not provided any objective evidence to support their position.

Although the reference is silent about "decreasing the production of a proteoglycan by a cell wherein the proteoglycan is selected from the group consisting of biglycan and decorin, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See MPEP 2145.

It seems reasonable on this record that the teachings of Dasch et al. on the use of TGF-β-specific antibodies to neutralize the effects of TGF-β, including lung fibrosis, liver cirrhosis fibrotic skin disorders and scarring would necessarily meet applicant's claimed methods, given the administration of the same agent (TGF-β-specific antibodies) in the same or nearly the same patients with the same or nearly the same fibrotic conditios associated with extracellular matrix formation.

Applicant's arguments are not found persuasive.

6. Upon reconsideration of applicant's arguments in conjunction with the the disclosure of the appropriate priority documents of the prior art, the previous rejection under provision of 35 U.S.C. § 103(a) as being unpatentable over Dasch et al. (U.S. Patent No. 5,772,998) in view of Ruoslahti et al. (U.S. Patent No. 5,583,103) AND/OR Bassols et al. (J.Biol. Chem. 263: 3039-3045, 1988) has been withdrawn as it applies to methods of treating glomerulonephritis with anti-TGF- β antibodies appears to be free of the prior art.

7. Claims 1-2, 5-7,10, and 13-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21 and 35 of copending application USSN. 08/349,479.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims of both the instant and copending applications are drawn to the same or nearly the same methods of treating glomerulonephritis with anti-TGF-β antibodies as they read on the elected invention.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant defers responding to the provisional rejection at this time.

8. Claims limited to methods of treating glomerulonephritis with anti-TGF-β antibodies appear to be free of the prior art.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571–273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
August 22, 2005